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TITLE: A Randomized Clinical Trial to Evaluate Advanced Nursing Care for Women with Newly Diagnosed Breast Cancer

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James J. Little
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10/20/95
Date

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INTRODUCTION

NATURE OF PROBLEM AND BACKGROUND OF PREVIOUS WORK

Breast cancer accounts for 32% of all cancers in women in the U.S. Greater than 183,000 new cases will be diagnosed in 1995 alone.¹ Cost-effective methods to manage breast cancer patients and to continue to achieve quality outcomes is therefore a major U.S. public health goal.

As costs decrease, it is unclear if quality outcomes are being maintained. In addition, factors including intricacy of the health care system, numerous caregivers, complexities of the diagnostic tests and procedures, and the technical components of treatment can overwhelm patients resulting in further compromised quality outcomes.

An Advanced Practice Nurse (APN) could serve as a facilitator to ease the breast cancer patient's way through the health care system providing quality care in a cost-effective manner. The Office of Technology Assessment (OTA) of the U.S. Congress conducted a comprehensive review of 286 studies on the cost and effectiveness of APNs. Their findings from this review indicated that within the APN's area of competence, they communicate better with patients, concentrate on prevention, and provide more education than physicians. Patients are satisfied with care, access to care is less complicated, and the costs of care are less with the interventions of the APN.²

Other studies including those which focused on lung cancer patients, low birthweight infants, MI patients, HIV-infected individuals, children with chronic diseases, and hospitalized elderly, have demonstrated the effectiveness of advanced nursing care with the results of improved outcomes and reduced health care costs, but none have focused on women with breast cancer.³⁻¹⁰

PURPOSE OF PRESENT WORK AND METHOD OF APPROACH

The purpose of this study is to test the following hypotheses:

- Women with newly diagnosed breast cancer who receive advanced nursing follow-up care/interventions will have a lower cost of care than patients who do not receive advanced nursing care.
- Women with newly diagnosed breast cancer who receive continuity of care through advanced nursing care/interventions across the various health care settings will achieve a better quality of life than patients who do not receive advanced nursing care.

The method of approach for this study is a randomized clinical trial to test these hypotheses using Brooten's model¹¹ to provide the framework for studying cost and quality of patient outcomes with the interventions of APNs. Modifications of this model have been made to clearly provide the framework of this study.

BODY - METHODS AND RESULTS

As defined in the proposal's statement of work, the following tasks were initiated and completed prior to beginning accrual, intervention, and data collection.

Preparation to Begin Study

Identification of Staff

Two nurses were hired who were near completion of their master of science degree in nursing, and met all other qualifications. A research assistant was hired and individuals were assigned to key positions for this study.

Quality of Life Data

Permission was granted to use the Profile of Mood States (POMS),¹² Mishel Uncertainty in Illness Scale (MUIS),¹³ and Functional Assessment of Cancer Therapy (FACT-B).¹⁴ These data collection instruments were prepared for initiation of the study and data entry bases were constructed and tested.

Demographic and Episodes of Care Data

A demographic form was developed to describe the patient population in the study and factors which may possibly be associated with the constructs and dimensions being measured.

Episodes of care in the diagnosis and treatment of breast cancer were identified and a "patient diary" was developed to record these episodes. (Appendix A) Episodes of care include physician visits, phone calls, emergency room visits, home care visits, etc. Each subject agrees to complete this diary when they decide to participate in the study.

Cost Data for Episodes of Care

Estimates for each episode of care have been identified and will be reported as charges and reimbursements. (For the purposes of this report, "cost" will include charges and reimbursements, as well as non-monetary costs.) The estimates will be further sub-divided into In-system and Out-of-system as well as cancer-related and non-cancer related. Whether a hospitalization is considered cancer-related or non-cancer-related will be determined by DRG code. Tables 1-3 indicate the source of the cost, charge or reimbursement information. (Appendix B) These estimates, combined with other episodes of care such as frequency of visits and telephone calls, obtained from the patient diaries and hospital/clinic computer systems, will make up the costs for each episode of care. When combined, we expect to have the total costs for the control and intervention arms of the trial.

The information obtained from the patient diary will be compared to the "gold standard" of information in the APN logs in order to determine the reliability of diary data. It is assumed that the control arm patient diaries will be similar to the intervention arm patient diaries with respect to reliability. Some external information exists for both intervention and control arm patients through our computer systems, so the number of clinic visits and length of hospital stay can be verified for both the control and intervention groups.

Cost Analysis Model

Paul W. Sperduto MD, MPP, alternate investigator; Jon Christianson, PhD, health economics consultant for HealthSystem Minnesota; and Laurel Decher, PhD, statistician and data coordinator, are developing the Cost Analysis Model for this study. The model is near completion and will be a model for this study and for future cost studies of women who are diagnosed with breast cancer. (Appendix C) Mock up tables have been prepared for the univariate analysis of the cost model. (Tables 1-3, Appendix B) Two indicators of cost (charges and reimbursement) are being evaluated in the model.

Education

The support and willingness of health care providers to work as a team with this study has exceeded all expectations. Support for this study has been further developed and will continue through communication and education throughout HealthSystem Minnesota.

Implementation of the Study

Experimental Methods

Patient enrollment began on February 15, 1995. Eligible women are approached about participating in the study, consent is obtained, and participants are randomized to one of two groups. Women in the control group receive the standard care which they would receive in the clinic, hospital, or patient's home. Women enrolled in the experimental group have an APN who begins follow-up immediately and continues follow-up for two years. All participants are asked to complete quality of life questionnaires at intervals of one week, one, three, six, twelve, eighteen, and twenty four months as well as the patient diary for the two year period.

Follow-up care and interventions of the APN based on Brooten's work¹¹ and the standards of advanced practice in oncology nursing¹⁵ include coordination of care, assessment and monitoring of symptoms, direct care, patient and family education, consultation with other health care services, utilization of current research findings, and establishment of standards of practice. Their interventions are further described in a summary which is given to the patient. (Appendix D) Interventions are being individualized within the limits of the protocol.

Accrual Status

A summary of the current accrual status is included in Table 4. (Appendix E) In the accrual of patients, the actual number of newly diagnosed breast cancer patients in our system of care is as projected. The actual number of participants is lower than projected. We have had a higher than anticipated number of ineligible patients. The reasons for ineligibility include 21 patients not enrolled in the study within one week of diagnosis, 19 patients with a previous diagnosis of cancer, and 15 patients receiving care outside our system. We have taken action to decrease the number of ineligible patients by proposing a modification to the study which would extend the enrollment time of the subjects from one week to two weeks following diagnosis. With that modification to the study, our actual number of eligible patients would reach our projected number. In addition, of the 26 patients not referred to the study, eighty-five percent (n=22) occurred in the first four months of the study. We feel physician referral of patients has been addressed and is no longer a problem.

Modifications of the Study

Enrollment of subjects within one week of their diagnosis has been difficult due to holidays, inability to talk with patients one-to-one, and wait time before patients are informed of their diagnosis by the physician. This constraining factor has lead to ineligibility of 21 of 63 (33%) patients. Approval for modifications to extend enrollment time of the subjects from one week to two weeks and the initial data collection and APN interventions from week one to as soon as feasible after enrollment of the subject into the study has been approved by our IRB. Approval is pending from the USAMRMC. We foresee more patients qualifying for the study and no changes in the study outcomes.

Collection of Data

Collection of data is being done as planned (week 1, months 1,3,6,12,18, & 24). Of the 30 participants who have been sent the month 3 mailings, 98% (88/90) of all questionnaires (week 1, month 1 , and month 3) have been returned. Demographic data and the data on the FACT-B, POMS, and MUIS are included. Episodes of care are being collected in the "patient diary" as previously described. (Appendix A)

Analysis of results of the study have not begun. However, in the accrual of participants, a preliminary observation was made that 12 of 41 (31.7%) study participants were diagnosed with depression and were being treated with antidepressant medications prior to the breast cancer diagnosis. These preliminary findings have prompted the investigation of the role of depression and/or antidepressant drugs as predisposing factors for breast cancer.

CONCLUSIONS

This study has been successfully initiated. With the cooperation, support, and work of the research staff and the health care providers within our system, we have defined a cost model for women diagnosed with breast cancer, enrolled 58 of 200 subjects into our four year study, are maintaining a high rate of return of all questionnaires, and have lost fewer participants to attrition than projected. Recruitment issues have been addressed and with USAMRMC approval of our proposed modifications in the eligibility criteria, enrollment into the study will reach our projections.

Our cost analysis is using two indicators, charges and reimbursement, for services. Further study is necessary to determine actual costs as compared to charges and reimbursement for the care of women with breast cancer. Our study provides a cost model which is paramount to evaluating actual costs for breast cancer care.

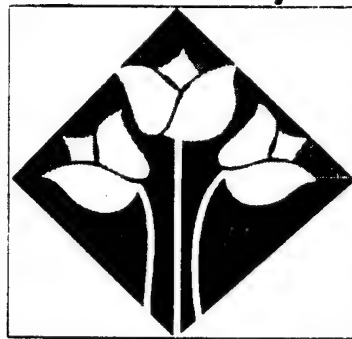
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DiARY



*A Randomized Clinical Trial
to Evaluate
Advanced Nursing Care
for Women With
Newly Diagnosed
Breast Cancer*

Appendix A

This is a diary especially designed for women with breast cancer. We request your cooperation in completing this diary. You will receive a new diary **every six months** for two years. Please answer questions relating to your experience over the next six months.

We are always trying to improve our quality of care. The information in this diary will help us to help you and others with breast cancer. Completion of this diary indicates your willingness and consent to assist us in collecting this information. If you have questions about this study, please call Laurie Ritz, R.N. at 993-6220. Thank you for your cooperation.

Laurie Ritz, R.N., M.S.N., O.C.N.

Paul W. Sperduto, M.D., M.P.P.

Diary Months _____ to _____

I.D.# _____

1. Name: _____

2. Date of Birth: _____ / _____ / _____
mo day yr

♦ Please complete questions 3-11 only if changes since the beginning of the study.

3. Date of Notification of Diagnosis: _____ / _____ / _____
mo day yr

4. Date of Surgery: _____ / _____ / _____
mo day yr

5. Name of Primary Doctor: _____

6. Name of Surgeon: _____

7. Name of Medical Oncologist: _____

8. Name of Radiation Oncologist: _____

9. Name of Plastic Surgeon: _____

10. Treatment:

Check all which apply:

Mastectomy	Yes	<input type="checkbox"/> 1	No	<input type="checkbox"/> 2
Lumpectomy	Yes	<input type="checkbox"/> 1	No	<input type="checkbox"/> 2
Radiation	Yes	<input type="checkbox"/> 1	No	<input type="checkbox"/> 2
Chemotherapy	Yes	<input type="checkbox"/> 1	No	<input type="checkbox"/> 2
Reconstruction	Yes	<input type="checkbox"/> 1	No	<input type="checkbox"/> 2

11. Way in which your breast cancer was detected:

Date detected _____ / _____ / _____
(Check one) mo day yr

Self	regular monthly exam	<input type="checkbox"/> 1
	accidental finding	<input type="checkbox"/> 2
Spouse/Other		<input type="checkbox"/> 3
Mammogram		<input type="checkbox"/> 4
Doctor		<input type="checkbox"/> 5
Other _____		<input type="checkbox"/> 6

12. Level of Activity during the week you receive this diary:
(circle only one number)

0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, i.e., light housework, office work.
2	Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50 percent of waking hours.
3	Capable of only limited self care. Confined to bed or chair more than 50 percent of waking hours.
4	Completely disabled. Cannot carry on any self care. Totally confined to bed or chair.

13. Hospitalizations—begin with the month you receive this diary:

[illegible]

14. Phone Calls—begin with the month you receive this diary:

[illegible]

15. Visits with Doctors and Nurses

—begin with month you receive this diary

Doctor or Nurse:	Date of visit:	Length of time of visit: (exclude wait time)		Wait Time: Time waiting to be seen by nurse, doctor.
		Start Time	End Time	Minutes:
Primary Doctor	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Surgeon	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Medical Oncologist	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Radiation Oncologist	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Plastic Surgeon	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Other Physician (Please write name in this space.)	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			

Doctor or Nurse:	Date of visit:	Length of Visit:		Wait Time: (Time waiting to be seen by nurse, doctor.)
		(exclude wait time)		
	mo / day / yr	Start Time	End Time	Minutes:
Nurse visits (i.e., chemotherapy)	/ /			
	/ /			
	/ /			
	/ /			
Nurse Practitioner Marcia Soules, RN, NP	/ /			
	/ /			
	/ /			
	/ /			
Nurse Coordinators Lynne Schroeder, RN or Mary Geditz, RN	/ /			
	/ /			
	/ /			
	/ /			
	/ /			
	/ /			

Was there anything which could have been
improved about your visits?

Yes ☐ 1

No ☐ 2

If yes, please identify: _____

16. Home Care Visits—begin with the month you receive this diary:

Type of Service (Doctor ₁ , nurse ₂ , nurse assistant ₃)	Date mo / day / yr	Length of Visit	
		Start Time	End Time
	/ /		
	/ /		
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	/ /		
	/ /		
	/ /		
	/ /		
	/ /		
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17. Urgent Care or Emergency Room Visits
—begin with the month you receive this diary:

Date mo / day / yr	Name of Urgent Care or ER		Reason
	Methodist ₁	Other, specify ₂	
/ /			
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18. Support services you use—begin with the month you receive this diary.

Type of Service	Yes	No	Number of Times
Cancer Support Groups/ Services (ie. Reach to Recovery)	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Other Support Groups	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Psychologist/Social Worker	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Sex Therapist	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Chaplain	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Dietitian	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Other: please specify	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>

19. Are you participating in another research study?

Yes ☐ 1 No ☐ 2

20. Are you undergoing physical therapy?

Yes ☐ 1 No ☐ 2

21. Are you using any alternative therapies such as hypnosis, vitamins, etc.?

Yes ☐ 1 No ☐ 2

If yes, please identify: _____

22. Are you employed outside your home?

Yes ☐ 1 No ☐ 2

If yes, how many hours per week are you employed?

23. Do you have children requiring daycare?

Yes ☐ 1 No ☐ 2

If yes, how many children do you have who require daycare?

How many hours of daycare time did you use per child and month prior to diagnosis?

_____ hours/month/child

_____ hours/month/child

_____ hours/month/child

_____ hours/month/child

24. How many hours of daycare time have you used per month since receiving this diary?

(Please answer this question in the chart provided on the next page).

25. How much time have you and your family members lost from work because of your diagnosis of breast cancer since receiving this diary?

(Please answer this question on the chart provided on the next page).

Please start recording information —begin with the month
you receive this diary.

	Daycare Hours per Month	Your Days Lost From Work	Family Members' Days Lost From Work
January			
February			
March			
April			
May			
June			
July			
August			
September			
October			
November			
December			
TOTAL			



Notes

Notes



A series of horizontal lines for writing notes, spanning the width of the page below the 'Notes' header.



Notes

 **Methodist Hospital**
HealthSystem Minnesota

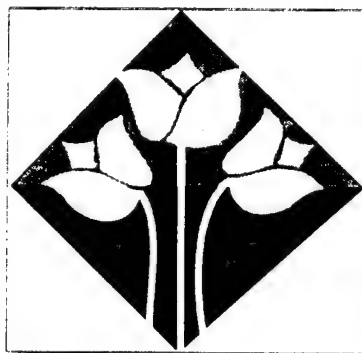


Table 1. In-System Cost Estimates

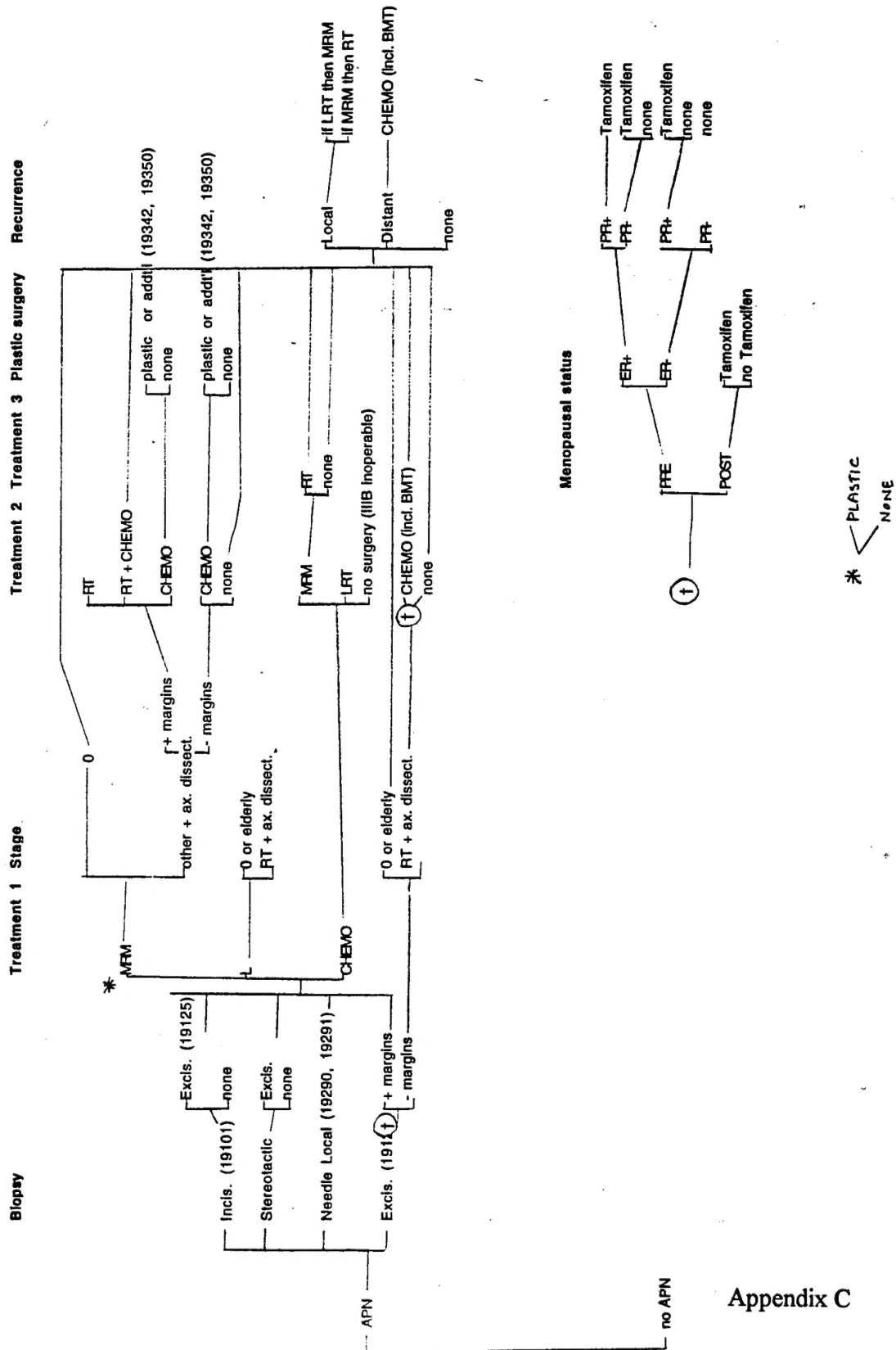
EPISODE OF CARE	CHARGE		REIMBURSEMENT	
	Median	Range	Median	Range
Treatment Choice				
Biopsy				
Mastectomy/ axillary dissection				
Lumpectomy/ axillary dissection				
Plastic surgery				
Radiation therapy				
Chemotherapy				
Professional fees				
Hospitalizations				
Methodist Hospital				
Professional fees				
Clinic Visits				
Park Nicollet				
Laboratory				
Diagnostic tests				
Home Care Visits				
Nurse or nurse assistant				
Physician				
ER or Urgent Care Visit				
Methodist Hospital				
Park Nicollet				
Professional fees				
Rehabilitation Services				
Physical Therapy				
Psychologist				
Sex therapist				

Table 2. Out-of-System Cost Estimates

EPISODE OF CARE	STANDARDIZED CHARGE		STANDARDIZED REIMBURSEMENT	
	Median	Range	Median	Range
Treatment Choice				
Tamoxifen				
Chemotherapy				
Independent physician visits				
Oncologists				
Surgeons				
Urgent Care or ER Visits				
Other Hospital or Urgent Care				

Table 3. Non-charge Estimates

EPISODE OF CARE	UNITS	AMOUNT
Rehabilitation Services		
Breast cancer support groups	Number of visits	
Other support groups	Number of visits	
Chaplain	Number of visits	
Psychologist (out-of-system)	Number of visits	
Social worker	Number of visits	
Sex therapist (out-of-system)	Number of visits	
Dietitian	Number of visits	
Hospitalizations		
Non-Methodist hospitals	Length of stay	
Telephone calls		
Nurse	Number of calls Length of calls	
Physician	Number of calls Length of calls	
Home Care Visits		
Nurse or nurse assistant	Number of visits	
Physician	Number of visits	
Referring physicians		
Family practice, internal medicine, other	Number of visits Length of visits	
Child care / lost work time		
Child care hours		
Lost work time for patient		
Lost work time for family		
APN time		
Telephone, administrative, travel time, home visits, patient visits	Mean salary + benefits for standard per minute charge	





BREAST CANCER NURSE COORDINATORS

Our goal is to assist you with your diagnosis of breast cancer. Possible ways in which we may assist you include the following:

- * Be a resource for you and your family
- * Offer you customized care tailored to your specific needs
- * Be an advocate for you based on your individual needs
- * Link with other members of the health care team to provide continuity of care for you
- * Offer you educational materials related to breast cancer and its treatment
- * Help you sort out confusing information
- * Increase your comfort level with making decisions
- * Help you determine what you need to ask the doctor at your next visit
- * Assess support needs for you and your family
- * Explain types of services available to Health Systems Minnesota patients
- * Help you figure out the types of services you and your family would like to have
- * Help you determine if you have emotional or financial needs that are not being met
- * Listen to your concerns and answer questions regarding any aspect of your cancer experience
- * Help you get through a bad day
- * Make referrals to support groups if needed
- * Monitor your physical status
- * Help you cope with physical changes your body is going through
- * Teach you about taking care of your health after your cancer care is completed
- * Help you learn to live with cancer

Please call us for any of your needs because we are here to help you. Please note the following hours, phone numbers and times we are available.

Lynne Schroeder, RN
Breast Cancer Nurse Coordinator
Methodist Hospital Cancer Center

Mary Geditz, RN
Breast Cancer Nurse Coordinator
Methodist Hospital Cancer Center

Monday - Friday
Weekends

8:00 am to 8:30 pm
8:00 am to 12:00 noon

Call Methodist Hospital at 932-5000
Ask the operator to page us

For nonurgent matters, feel free to call
and leave a message on our voice mail at 932-6030

Appendix D

Table 4. Accrual Status

	n-Projected (%) at 1 yr.	n-Projected (%) at 8 mths	n-Actual (%) at 8 mths
Newly diagnosed breast cancer patients in the system of care	250	167	170
Referred	200 (80%)	134 (80%)	144 (85%)
Eligible	150 (75%)	100 (75%)	81 (56%)
Refused	25 (17%)	17 (17%)	23 (28%)
Participants enrolled from eligible	125 (83%)	83 (83%)	58 (72%)
Lost to attrition	25 (20%)	17 (20%)	5 (9%)
Total participants	100 (80%)	66 (80%)	53 (91%)